B·DEBATE International Center for Scientific Debate BARCELONA

IBEC Institute for Bioengineering of Catalonia

ANTONIO GUZMÁN

CV

PARTICIPANT AT:

FUTURE TOOLS FOR BIOMEDICAL RESEARCH. IN VITRO, IN SILICO AND IN VIVO DISEASE MODELING

October, 1st-2nd, 2015, Barcelona

Antonio Guzmán, Head of Toxicology Department, ESTEVE. Barcelona Science Park, Barcelona, Spain.

Graduate in Biological Sciences and Ph.D. in Genetics from the Autonomous University of Barcelona. University Expert in Toxicology (Seville University) and EUROTOX registered Toxicologist. He is responsible for all non-clinical safety assessment activities conducted from early candidate selection to regulatory toxicology testing and post-approval activities. As non-clinical toxicology expert he is involved in preparing technical reports and regulatory documents to support safety aspects of ESTEVE's R&D projects (NCEs and ATMPs) and marketed products, and interacting with regulatory agencies. Author of several publications on non-clinical safety assessment of drug candidates in peer reviewed journals, reviewer in several scientific journals and invited lecturer in several Scientific Society Meetings and University Master Degrees. He is member of several scientific societies: the Spanish Environmental Mutagenesis Society (SEMA), the Spanish Laboratory Animal Science Society (SECAL) and the Spanish Toxicology Society (AETOX).

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ABSTRACT

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Use of Alternative Methods in Drug Safety Assessment.

Drug discovery and development is a complex and time consuming process in which non-clinical toxicology testing is a pivotal component. During the early candidate selection phases the conducted toxicology screening studies allow selecting those compounds showing the most favourable safety profile. In vitro screening studies are consequently designed to assess an extensive number of molecules within a short time period and with a limited use of compound. To support clinical development, regulatory toxicology studies are conducted both in advance and in parallel to clinical studies, aiming to characterize the toxicological profile of the drug candidate and identifying potential risk for human toxicities and parameters for clinical monitoring. While far from optimal, animal models still play a pivotal role in regulatory toxicity testing. However, in the last decades there has been an ever growing role for the use of alternative models (in vitro and in silico) as part of the safety assessment required by regulatory authorities.

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